

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Ronald A. Guzman	Sitting Judge if Other than Assigned Judge	Geraldine Soat Brown
CASE NUMBER	99 C 1492	DATE	5/11/2001
CASE TITLE	Muller vs. Synthes Corp.		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

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DOCKET ENTRY:

- (1) ☐ Filed motion of [use listing in "Motion" box above.]
- (2) ☐ Brief in support of motion due ____.
- (3) ☐ Answer brief to motion due _____. Reply to answer brief due _____.
- (4) ☐ Ruling/Hearing on _____ set for _____ at _____.
- (5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.
- (6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.
- (7) ☐ Trial[set for/re-set for] on _____ at _____.
- (8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.
- (9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).
- (10) ☒ [Other docket entry] Defendants' motions to exclude testimony of plaintiff's experts, Gerald Uhland and Robert O. Andres [24-1] [28-1] are granted. Enter Memorandum Opinion and Order.
- (11) ☒ [For further detail see order (on reverse side of/attached to) the original minute order.]

Geraldine Soat Brown

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

REBECCA MULLER,
Plaintiff,

v.

SYNTHES CORP., et al.
Defendants.

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Cause No. 99 C 1492

Magistrate Judge Geraldine Soat Brown

DOCKETED
MAY 15 2001

MEMORANDUM OPINION AND ORDER

This cause is before the Court on Defendants' Motions to Exclude Testimony of Plaintiff's Experts, Gerald Uhland and Robert O. Andres. [Dkt ## 24, 25, 28.]¹ By consent of the parties under 28 U.S.C. § 636(c), this Court's Opinion and Order shall be the final ruling on the motions. [Dkt ## 29, 30.] For the reasons set forth below, Defendants' motions are GRANTED as to both Plaintiff experts.

1. Plaintiff's Claim

This is a product liability case involving a medical implant device to aid healing after cervical spine surgery. Plaintiff Rebecca Muller ("Muller" or "Plaintiff") brings this action against

¹ Citations to court papers and other documents are as follows:

- "Dkt #" refers to the Docket Number.
- "R. __" refers to the sequentially numbered pages of the transcript of proceedings on Defendants' motion, held on March 27, 2001.
- "Andres" refers to the August 29, 2000 deposition of Plaintiff expert Robert O. Andres, and exhibits.
- "Bauer" refers to the September 9, 1999 deposition of Plaintiff treating physician Jerry Bauer, M.D., and exhibits.
- "Shapiro" refers to the October 2, 2000 report of opinion of Defendant expert Scott A. Shapiro, M.D.
- "Uhland" refers to the August 9, 2000 deposition of Plaintiff expert Gerald E. Uhland, and exhibits.

the manufacturer of the device, Synthes Spine Company, L.P., and the manufacturer's United States affiliate, Synthes (U.S.A.) (collectively "Synthes" or "Defendants"). Plaintiff claims the device is defective because it was found to have fractured on both of two occasions after it was implanted in Plaintiff following a surgical procedure known as an anterior spinal discectomy and fusion. (Am. Compl. at ¶¶ 3, 7.) [Dkt #2.]

The device, a cervical spine locking plate ("CSLP"), is a titanium plate that is held in place by several screws. The CSLP has an "H" shape, with four screw holes and a fifth, center hole. (Uhland Ex. 3, Figure 1.) Defendant's product labeling for the CSLP states as its first usage warning that the CSLP is intended to provide only temporary support while the bone is healing. The warning states that if healing is prolonged, the CSLP may crack. (Bauer Ex. 2.)

Muller underwent surgery to correct deterioration of her cervical spine. She elected to have a bone graft from a cadaver, rather than grafting bone taken from her hip. (Bauer at 46.) A cadaver bone graft has more risk of collapsing and failing to fuse with the existing bone structure than does live bone. (Shapiro at 1-2.) Muller had a prior medical condition that required her to take the medication Prednisone, which can interfere with bone growth and bone healing. (Bauer at 47-48.) Muller underwent surgery in February, 1997. The CSLP was implanted at this time. (Bauer at 49.)

Muller reported no post-surgical problems with the implant, and x-rays taken two weeks after the surgery showed satisfactory results. (Bauer at 58-60.) Another x-ray a month later showed no change. (Bauer at 62.) Muller went in for a follow-up exam in May, 1997. X-rays taken at this time showed the CSLP had fractured. (Bauer at 64-65.) Because the x-ray also showed slow healing and some compression of the cadaver bone graft material, the surgeon operated a second time, in July, 1997, to replace the fractured CSLP. (Bauer at 76-78, 82.)

Again, Muller reported no post-surgical complications. (Bauer at 94-95, 100.) Ten months

after the second surgery, in May, 1998, Muller underwent x-rays for another medical problem. Coincidentally, the x-rays showed the second CSLP also had fractured. (Bauer at 99-100.) There was no indication how long previously the fracture had occurred. Since Muller was not complaining of any problem relating to the cervical spine bone graft, and since the graft now appeared to have set properly, the surgeon decided not to remove or replace the fractured CSLP. (Bauer at 100-01.) The device remains implanted in Plaintiff at the present time. (Bauer at 27-28.)

Muller sued in 1999, alleging strict product liability, as well as various UCC and common law theories of breach of warranty of merchantability and fitness for a particular purpose. (Am. Compl. at ¶7.)

2. Plaintiff's Proposed Experts

In discovery, Plaintiff's counsel disclosed two experts, Gerald Uhland, a metallurgist whose specialty is heat treating and brazing of metals used in manufacturing (large) machinery, and Robert Andres, whose specialty is ergonomics and bioengineering. (Uhland at 4, 28-29, Ex. 2; Andres at 6.) Uhland and Andres had both been retained to testify previously in other cases against Synthes. Their testimony (two cases for each of them) either was excluded or narrowly limited in a way that made it irrelevant to key issues. (Uhland at 7-10; Andres at 21-22, 65-66.) For both Uhland and Andres, these prior cases against Synthes were the only previous occasions where they sought to testify in a case involving a medical implant device. (Uhland at 10; Andres at 20.) Their other experience as experts involved primarily large machinery, vehicles, implements, and the like. Uhland testified he has done failure analysis on everything from hypodermic needles to construction cranes and steam turbines. (Uhland at 30.) Andres has testified on product defects involving trucks, truck trailers, trenching machines, wood chippers, and exercise equipment. (Andres at 18.)

Uhland sought to testify previously regarding a Synthes lumbar spine device and a Synthes cervical spine device (not the CSLP, but similar to it.) In both cases he sought to give opinions on design issues as well as other matters. In one case he was allowed to testify to other matters, but not design issues. In the other case his testimony on design issues initially was allowed, but then was stricken. (Uhland at 7-10.) Andres' two prior Synthes cases both involved the CSLP. His testimony was barred in one case. In the other case (one of those in which Uhland testified at trial), Andres was deposed but claims the case settled and he did not testify at trial. (Andres at 21-22, 65-66.)

Uhland, the metallurgist, was involved in design work only for a few years after college. His involvement in design appears to have been peripheral. Uhland has no training or experience in design of medical implant or any other medical devices. (Uhland at 21-25.) Andres, the ergonomics specialist, also has no training or experience relating to design of medical implant or other medical devices. (Andres Ex. 1.)

3. The Experts' Proposed Testimony

a. Uhland

Plaintiff's counsel instructed Uhland that any tests he performed on the CSLP removed from Plaintiff must not alter the device in any way. Uhland complied with this stricture by limiting himself to conducting a hardness test, and to looking at the device with the naked eye and at photographs, x-rays, and examination of images produced by a scanning electron microscope. (Uhland at 32-35, Ex. 3 at 1.)

Uhland's hardness tests confirmed that the CSLP was made of titanium. (Uhland at 35-36, Ex. 3 at 2.) Beyond this fact, all of Uhland's opinions are based on looking at the CSLP. He concluded the CSLP fractured because of bending stresses. However, he concluded the bending

stresses were not due to improper installation by the surgeon, because he saw no evidence of fretting around the screw holes. Further, he concluded the fracture was not a fatigue fracture caused by normal bending stresses. (Uhland at 45, 49-50, 57-58, Ex. 3 at 3.)

Uhland concluded that the “H” shape, the narrowness of the midsection, and the hole in the midsection of the device made the CSLP subject to fracture. He arrived at these conclusions without any attempt to learn why the CSLP was shaped as it was, or the purpose of the central hole in the device. (Uhland at 73-76.) He made no apparent inquiry into medical literature on how the device was intended to function, what stresses it was subject to, or how long it was intended to function (Uhland at 62-63), nor did he attempt to witness a surgical implant of the device, or acquire any information about how bones heal (or why their healing might be impeded) and how bone grafts work (or why they may fail). (Uhland at 61-65, Ex. 3 at 3.)

In addition to the Plaintiff’s CSLP, Uhland examined several other fractured CSLPs. However, he made no attempt to learn how many of Synthes’s devices have been implanted in humans, or what the failure rate might be. (Uhland at 77-78.)

Despite his limited inquiry, Uhland concluded that faulty design alone caused Plaintiff’s CSLP to fracture. (Uhland Ex. 3 at 3.)

b. Andres

Andres arrived at his conclusions by reading Synthes information on the CSLP, and research literature pertaining to the use of spinal locking plates. (Andres at 64-65.) The research literature Andres cites, however, deals with devices different from the CSLP, or deals with medical circumstances different from those of Plaintiff. (Andres at 82-90, 134-38, 143-50, Ex. 4 at 7-8.) In addition, Andres gauged the load-bearing capacity of the CSLP by applying a general stress analysis

method that Andres claims would apply to any type of device. (Andres at 105.) As to medical devices for treatment of bone, he knows the stress analysis is applied to long bone plates and prosthetics, but is not aware of any studies using this analysis for cervical spine implant devices. (Andres at 102-07, Ex. 4 at 4.) He applied this standard analysis to the CSLP on the assumption the device itself must be able to support the entire weight of the head, without taking into consideration the support provided by any skeletal or musculature components. (Andres at 116-20.)

Andres admits he has no special knowledge of, and has made no study of, matters pertaining to bone degeneration and healing, the cervical spine, the normal pressures exerted on the cervical spine, and similar topics. He did not review Plaintiff's x-rays, and knows nothing about the surgical procedure for implanting the CSLP. (Andres at 78-82.)

Andres cites one ergonomic study relating to the number of head flexions experienced by female workers in an electronics assembly plant, though he admits the study has no relevance to head flexion in ordinary circumstances of daily life. (Andres at 134, Ex. 4 at 7.) Andres concludes the CSLP should have been made thicker, by which he means the central hole should be eliminated. (Andres at 124-25.) He regards the hole in the midsection as a design flaw, though he does not know why the hole is there. (Andres at 121-22, 124, Ex. 4 at 9.) Finally, he concludes that the warning label Synthes places on the CSLP package, which states that the CSLP may break as a result of metal fatigue if bone healing is delayed, was an attempt by Synthes to deal with the flawed design of the CSLP through a warning label rather than by redesigning the product. (Andres Ex. 4 at 9.) He reaches this conclusion apparently without any basis except his own view that Synthes should produce "layman type of information." (Andres at 155, 158-61, Ex. 4 at 8.)

Defendants note that although Defendants made timely disclosure of their testifying experts, Plaintiff neither has objected to nor deposed these witnesses. (R. 13.) At oral argument on

Defendants' motion to exclude experts, counsel for Defendants pointed out that, if Plaintiff had deposed Defendants' expert, Plaintiff's experts would have learned a number of things about the CSLP that they did not know. Defendants' counsel listed, among other points of information, the reason for the H-shaped design, the center hole, and the choice of thickness of metal for the CSLP, which were design features Plaintiff's experts criticized as being defective. (R. 32-33.)

Defendants' counsel indicated, for example, that Defendants' disclosed expert was prepared to testify that the center hole in the CSLP had three purposes: 1) to act as an insertion point for a tool used to hold the CSLP in place while the surgeon inserted the four screws; 2) to provide a viewing port necessary for inspecting the progress of bone healing beneath the CSLP; and 3) to provide an optional extra screw hole, if needed because of bone deterioration. (R. 32-33.)

Counsel for Plaintiff conceded that neither of Plaintiff's experts knew, for example, the design purpose of the center hole in the CSLP, nor was counsel aware of any study made by Plaintiff's experts either to determine the purpose for the hole in the CSLP or to design and test an alternative to the CSLP. When the Court questioned what scientific basis Plaintiff's experts had, then, for concluding that the center hole (and the thickness of the metal) was a design flaw in the CSLP, counsel for Plaintiff answered that the experts based their conclusions on "more of a logic thing" rather than on any independent testing of an alternative design. (R. 24-26.)

4. Legal Analysis

Beginning in 1993 the United States Supreme Court issued a trilogy of decisions emphasizing the trial court's important role as a "gatekeeper," to screen out purported expert testimony that is not both relevant and reliable. The first of these decisions was *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *Daubert*, a toxic tort case, described the analysis

federal courts are to use when determining the admissibility of testimony by purported scientific experts under Fed. R. Evid. 702. This analysis includes a non-exhaustive list of four factors to be considered in order to ensure that purported scientific testimony is tied sufficiently to the facts of the case on the one hand, and on the other hand is grounded in the methods of science. (*Id.* at 590-92.)²

In the second case in the trilogy, the Supreme Court held that abuse of discretion is the correct standard for an appellate court to apply in reviewing the trial court's decision whether to exclude expert testimony. *General Electric Co. v. Joiner*, 522 U.S. 136, 141-43 (1997).

The third case in the trilogy held that the trial court's gatekeeper role applies not only to proposed scientific expert testimony, but also to proffers of expert testimony regarding technical or other specialized knowledge. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). In *Kumho*, the Court emphasized that in exercising its gatekeeper function, the trial court must make certain that, whether the proposed expert seeks to base his testimony on professional studies or entirely on personal experience, the expert must employ the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. (*Id.* at 152.)

Subsequent to *Kumho*, the federal evidentiary rule on admissibility of expert testimony was amended to incorporate the concepts contained in *Daubert* and its progeny. Federal Rule of Evidence 702 now provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise *if (1) the testimony is based upon sufficient facts*

² The four factors of *Daubert* are: 1) whether the expert's proffered theory is scientific knowledge that will assist the trier of fact and can be tested; 2) whether the theory has been subjected to peer review or publications; 3) the known or potential rate of error and the existence of standards controlling the technique's operation; and 4) the extent to which the technique employed by the proposed expert is generally accepted in the scientific community. *Daubert*, 509 U.S. at 593-94.

or data, (2) the testimony is the product of reliable principles and methods, (3) the witness has applied the principles and methods reliably to the facts of the case.

(Italics added to denote amendment to statute.)

The testimony proffered by Uhland and Andres does not meet any of the criteria of Rule 702.

a. Insufficient facts

Both Uhland and Andres rely on a cursory fact inquiry to reach their conclusions that the CSLP is a defective design. Neither witness has any experience with or has made any study of medical implants in general or cervical spine locking plate devices in particular. Neither witness has any specialized knowledge of or has made any study of medical issues in general or issues relating to discectomy and fusion of the cervical spine. Neither witness knows anything about the procedure for implanting the CSLP, or has made any inquiry into what medical science considers to be a successful implant of the device, or what are the expectations of medical science as to the range of stresses the device normally should withstand, how long the device is expected to function under this range of normal stresses, and to what degree the device is expected to continue functioning adequately if the patient experiences slow bone healing or similar complications following surgery.

Without knowledge of such information, it is unlikely that any testimony the witnesses might offer about whether the CSLP is a defective design could be either relevant or reliable. Uhland and Andres may well have expertise in certain areas of technical specialty. Uhland's experience has been with metal failure in association with heat treating and brazing. Andres has experience with bioengineering issues in regard to operation of vehicles, machinery, and large implements. However, these areas are not relevant to the issues in this case.

An expert must be limited to opinion testimony in the area of expertise for which the proffering party can qualify the expert. *Goodwin v. MTD Products, Inc.*, 232 F.3d 600 (7th Cir.

2000) (plaintiff's expert, a mechanical engineer, was qualified to testify whether use of plastic wing nut was design defect, but defendant's design engineer was not qualified to testify to medical question whether broken wing nut could cause plaintiff's type of eye injury).

Once qualified, the expert can testify to his or her area of expertise, regardless of whether the expert is prepared to offer an opinion as to the ultimate issue. *Smith v. Ford Motor Company*, 215 F.3d 713 (7th Cir. 2000.) In *Smith v. Ford*, the trial court excluded testimony from two automotive engineers in a case involving a defective steering gearbox on an automobile. One expert proposed to testify regarding design issues, the other regarding manufacturing issues. However, neither expert was able to say whether ultimately it was defects in the design or defects in the manufacture that caused the steering box to fail. The trial court excluded their testimony because they could not testify to this ultimate conclusion. The appellate court reversed the trial court's exclusion of this testimony, holding that testimony of a qualified expert is admissible if it addresses an issue pertinent to the case. The expert is not required to testify to the ultimate issue. (*Id.* at 721.)

Unlike the experts in *Smith v. Ford*, here Plaintiff's experts propose to testify to the ultimate issue of whether the CSLP has a flawed design, but do not have the factual basis to give an opinion on that matter.

b. Unreliable principles and methods

Plaintiff's experts also fail to apply reliable scientific or technical principles and methods in arriving at their conclusions that the CSLP is a flawed design. Both experts conclude the CSLP design is flawed because the titanium metal used is too thin, and because of the center hole in the device, for which the experts perceive no function. Uhland arrived at his conclusions based on an examination of the device using the naked eye and an examination of conventional photographs, x-

rays, and electron microscopic photographs, apparently of the first fractured CSLP that was removed from the Plaintiff. Uhland did not attempt any other studies to assess, for example, the ability of the device to withstand bending fatigue. He elected not to do so purportedly because Plaintiff's counsel instructed Uhland not to do any destructive testing on the CSLP removed from the Plaintiff. Uhland does not explain what prevented him from performing such tests on a CSLP other than the one that had been implanted in and removed from Plaintiff.

Andres arrived at his conclusions about the purported design defects based on application of an elementary, general computation used for determining the maximum stress an object can withstand. Andres justified use of this rudimentary computation based on the fact that it has been applied to objects of all types and sizes. As to medical devices, however, he only knew that this test was used on prosthetic devices relating to long bones of the leg. Moreover, he performed his calculation based on the assumption that the cervical spine vertebrae (and apparently, therefore, also the CSLP) must bear the entire load of the weight of the person's head, without any weight-bearing contribution from muscles or ligaments or other skeletal structures, although Andres admitted that, in reality, the muscles and ligaments share the load. (Andres at 120.)

In a case cited by Plaintiff in opposition to Defendants' present motion, the Seventh Circuit Court of Appeals commented on the degree of intellectual rigor required to qualify expert testimony. *Tuf Racing Products, Inc. v. American Suzuki Motor Corporation*, 223 F.3d 585 (2000). The court in *Tuf* noted that the Supreme Court's *Daubert* decision did not limit expert testimony only to testimony based on some type of scientific expertise. The *Tuf* court concluded that testimony of a certified public accountant qualified as admissible expert testimony, where the issue was what financial impact the defendant manufacturer's termination of plaintiff as a distributor for defendant's motorcycles had on plaintiff's motorcycle dealership. (*Id.* at 591.) The Court in *Tuf* emphasized,

however, the principle of *Daubert* that, where a party proffers testimony of an expert that purportedly is based in science, the science applied by the proposed expert “must be real science, not junk science.” (*Id.*)

Likewise, the Supreme Court’s *Kumho* decision emphasizes the trial court’s gatekeeper role to make certain that, whether the expert purports to base his testimony on professional studies or personal experience, the expert must “employ in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho*, 526 U.S. at 152.

In the present case, merely examining the fractured CSLP with the naked eye, or even with electron microscopic photographs, and utilization of a simplistic stress computation that fails to consider relevant factors cannot, by themselves with nothing more, constitute employment of the rigor that characterizes the practice of experts on design of medical implant devices such as the CSLP.

The testimony of Uhland or Andres can be of no aid to the finder of fact, as suggested by the argument of Plaintiff’s counsel that Plaintiff’s experts based their conclusions that the CSLP is a defective design on simple “logic.”

c. Unreliable Application of Principles and Methods

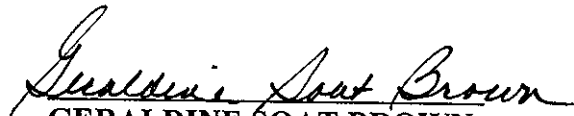
Where, as here, Plaintiff’s experts conclude that the CSLP must be redesigned to incorporate thicker metal and to eliminate the center hole, it is not enough for the witnesses merely to make general suggestions about the redesign. If Plaintiff’s experts wish to testify about an alternative design of the CSLP, they are required to offer more than mere subjective belief or unsupported speculation. *Bourelle v. Crown Equipment Corp.*, 220 F.3d 532 (7th Cir. 2000). Instead, they must be able to present evidence of their proposed alternative design that demonstrates the same rigor that

an expert would apply who works in the field of designing medical implant devices such as the CSLP. (*Id.* at 537.) As in *Bourelle*, Plaintiff's experts here made no attempt at all to reach the level of technical specificity and rigor required of a design engineer. Uhland and Andres offer no specific alternative design, they have no detailed design calculations or specifications, they have made no preliminary design drawings. Perhaps most important, they have made no attempt to test their theory that using thicker metal and eliminating the center hole will correct the purported design flaws of the CSLP without also compromising the device's utility as an aid to bone healing in cervical spinal fusion procedures.

In *Bourelle*, the Court of Appeals upheld the exclusion of purported expert opinion where the expert had no experience with the device and had never tested his alternative design. 220 F.3d at 536-39. Likewise, this Court must exclude the proposed testimony of Plaintiff's experts Uhland and Andres, where their generalized conclusions about design alternatives to the CSLP make no attempt to apply any recognized principles of design. Their testimony about possible alternative designs is neither relevant nor reliable.

Plaintiff's experts come nowhere near satisfying the standards for expert testimony required under Fed. R. Evid. 702. Accordingly, Defendants' motion to exclude the testimony of Uhland and Andres is granted.

IT IS SO ORDERED.


GERALDINE SOAT BROWN
United States Magistrate Judge

DATED: May 11, 2001